REMARKS

Claims 32-45 are pending in the subject application, with claims 41 and 44-45 withdrawn from consideration. By this Amendment, applicants have canceled claims 41, and 44-45 without prejudice or disclaimer to applicants' right to pursue the subject matter of these claims in a future continuation or other application. In addition, applicants have hereinabove amended claims 32, 33, 46, 37, 38, 39, 40, 42, and 43. Applicants maintain that the amendments to the claims raise no issue of new matter. Support for amended claim 32 can be found in the specification as originally filed at, inter alia, page 6, lines 4-7; page 10, line 10; and page 5, line 30 to page 31. Support for amended claim 33 can be found in the specification as originally filed at, inter alia, page 6, lines 4-7; page 10, line 10; and page 5, line 30 to page 32. Support for amended claim 36 can be found in the specification as originally filed at, inter alia, page 13, line 29. Support for amended claim 37 can be found in the specification as originally filed at, inter alia, page 13, line 29. Support for amended claims 38 and 39 can be found in the specification as originally filed at, inter alia, page 6, lines 4-23; page 3, lines 27-33; and page 3, lines 11-12. Support for amended claim 40 can be found in the specification as originally filed at, inter alia, page 3, lines 8-12; page 1, lines 20-24; page 6, lines 4-14; page 3, lines 11-12; and page 10, lines 10 and 17. Support for amended claims 42-43 can be found in the specification as originally filed at, inter alia, page 7, line 26 to page 8, line 1; and page 10, line 17. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 32-40, and 42-43 will be pending and under examination.

Claim Rejections under 35 U.S.C. §112, Second Paragraph

In the July 2, 2003 Office Action, the Examiner stated that claims 40, 42, and 43 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Examiner stated that the omitted steps are: the administering, dosage and route etc.

In response, applicants respectfully traverse the Examiner's rejection. More specifically, applicants maintain that claims 40, 42 and 43 are not incomplete, and that the claims clearly set forth the essential steps of the claimed invention. The administered dosage would be clearly understood by one of skill in the art from the claim terms reciting the effective amount sufficient to treat the disease in the subject. The specification clearly teaches such dosages e.g. see page 10, line 28 to page 12, line 20 and routes of administration to a subject i.e. orally or intramuscularly, e.g. see specification as page 10, lines 16-19. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have amended claims 40, 42, and 43, to specify oral administration. Accordingly, applicants maintain that the claims do not omit essential steps, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections under 35 U.S.C. §103(a)

The Examiner stated that claims 32, 38, 40, 42 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. (Patent No. 4,816,563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86). The Examiner stated that the claimed invention is drawn to a composition and a method for

using the composition to treat chronic fatigue syndrome (CFS) patients, wherein the composition comprises a cell free secretion from a mammary gland secretion or a lyophilized product of the cell-free fluid from an animal infected with human herpesvirus-6A and human herpesvirus-6B. The Examiner further stated that Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The Examiner stated that the TF is extracted from spleens of BALB/c mice immunized with EBV, CMV, and HHV-6 live virus. The Examiner stated that because the transfer factor can produce activity across species, injection of the isolated TF significantly alleviates the clinical symptom of the patients suffering from chronic fatigue syndrome (CFS) caused by HHV-6 infection (see entire document). The Examiner stated that Ablashi et al. do not teach to use cell free product secreted from a mammal, which contains the antigen specific TF against HSV-6 or HSV-5. The Examiner further stated that Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from colostrum or milk of a bovine, and it can be lyophilized and stored dry for later use and/or reconstituted in sterile pyrogen-free water, physiologic saline or any other fluid suitable for injection or oral administration (lines 26 on col. 5 through line 68 on col. 6). The Examiner stated that Wilson et al. also teach that the antigen specific TF is used for enhancing the cellular immunity against specific antigens to which the TF-producing animal is immunized, such as herpes simplex virus, Newcastle's disease, Marek's disease etc.

The Examiner further stated that, therefore, it would have been obvious for a person skilled in the art at the time the application was filed to be motivated by Abashi et al. and Wilson et al. to use the TF derived from the milk or colostrum product for treating the CFS because the TF derived from a mammal milk

product would be much easier and economic to be accepted by patients or market. The Examiner stated that hence the claimed invention as a whole is *prima facie* obvious absent unexpected results.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claims 32, 33, and 40 to recite a cell-free fluid consisting essentially of a mammary gland secretion of a human herpesvirus-6A (or 6B) immunized lactating mammal. Applicants note that Ablashi et al. does not teach a cell free fluid of a mammary gland secretion consisting essentially of a human herpesvirus-6A infected lactating mammal (nor herpesvirus-6B infected) as claimed by applicants, but rather teaches a spleen-derived general transfer factor for all of EBV, HHV-6 (not specific subtypes) and CMV. In addition, Wilson et al., does not disclose HHV-6A or HHV-6B specific transfer factor and does not remedy this deficiency. Moreover, applicant notes that the claimed subject matter is unexpectedly successful in treating Chronic Fatigue Syndrome (CFS). Whereas Ablashi teaches that 50% of patients suffering CFS treated with the general transfer factor for EBV, HHV-6 and CMV showed some symptomatic relief (see Abstract), applicants disclose the claimed subject matter showed symptomatic relief in 90% of patients when administered to CFS patients (see page 12, lines 14-15). Wilson et al. does not remedy this deficiency. Applicant also notes that Ablashi et al. teaches no control experiment.

Accordingly, applicants maintain that the rejected claims define an invention not obvious from the cited references, and therefore not properly rejected under 35 U.S.C. §103(a), and respectfully request that the Examiner reconsider and withdraw this ground of rejection.